

In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 03-1455V

Filed: September 19, 2013

Not to be Published

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ANGELA SCHAFFER \*
Individually and as Next Friend of, \*
KYRA DENISE SCHAFFER, a minor \*

Petitioner, \*

Autism; Statute of Limitations;
Untimely Filing

v. \*

SECRETARY OF HEALTH AND \*
HUMAN SERVICES, \*

Respondent. \*

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Michael T. Gallagher, Esq., The Gallagher Law Firm, Houston TX, for petitioner.
Linda S. Renzi, Esq., U.S. Dept. of Justice, Washington, DC, for respondent.

DECISION1

Vowell, Special Master:

On June 12, 2003, Angela Schaffer ["petitioner"] filed a petition for compensation under the National Childhood Vaccine Injury Act2 ["Vaccine Act"] on behalf of her daughter, Kyra Denise Schaffer ["Kyra"]. No medical records were filed with the petition. Petitioner alleges that Kyra "received a series of mercury-containing vaccines and . . . subsequently demonstrated developmental problems." Petition at 1. Petitioner

1 Because this unpublished decision contains a reasoned explanation for the action in this case, I intend to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioners have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

2 The National Vaccine Injury Compensation Program comprises Part 2 of the National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755, codified as amended, 42 U.S.C.A. §§ 300aa-10 et. seq. (2006). All citations to the Vaccine Act in the decision will be to 42 U.S.C. § 300aa.

contends that her claim is timely filed or that, in the alternative, the doctrine of equitable tolling should be applied to her claim because she did not and could not know the factual basis for her claim. *Id.*

## I. Procedural History.

Petitioner's claim was included in the Omnibus Autism Proceeding ["OAP"].<sup>3</sup> Thus, this case was effectively stayed while the general causation issues were litigated in the OAP.<sup>4</sup> See Notice, filed July 7, 2003, at 1. During the period between the test case hearings and final appellate action on the test case decisions,<sup>5</sup> petitioner, like others in the OAP, was ordered to file the medical records needed to establish that the petition was timely filed. Order, filed Nov. 14, 2008, at 1; see also § 16(a)(2) (the Vaccine Act's statute of limitations). Once records were filed, respondent was directed to file a statement indicating whether petitioner's claim should continue in the OAP. Order, filed Nov. 14, 2008, at 5-6.

In February 2009, petitioner filed some medical records. See Petitioner's Exhibits ["Pet. Exs."] 1-2. In response, respondent filed a motion to dismiss petitioner's claim. Respondent asserts that Kyra exhibited symptoms of autism on January 14, 2000 or earlier and, therefore, the claim was filed more than six months after the expiration of the Vaccine Act's statute of limitations. Respondent's Motion to Dismiss ["Res. Motion to Dismiss"], filed Mar. 20, 2009, at 1, 5. In her motion to dismiss, respondent also argued that equitable tolling is not applicable to Vaccine Act claims.<sup>6</sup> *Id.* at 6-7.

On May 12, 2009, petitioner filed a response to respondent's motion to dismiss, arguing that the statute of limitations did not begin to run until Kyra's condition was recognized by a medical professional when she was formally diagnosed with autism on July 16, 2001.<sup>7</sup> Petitioner's Response to Motion to Dismiss ["Pet. Response"] at 1-2, 6-

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<sup>3</sup> Petitioner's claim fell within the second theory of causation ["Theory 2"] litigated in the OAP. A detailed discussion of the OAP can be found at *Dwyer v. Sec'y, HHS*, No. 03-1202V, 2010 WL 892250, at \*3 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

<sup>4</sup> The Petitioners' Steering Committee ["PSC"], an organization formed by attorneys representing petitioners in the OAP, litigated six test cases presenting two different theories on the causation of autism spectrum disorder ["ASDs"].

<sup>5</sup> The final appellate decision on Theory 1 test cases was issued on August 27, 2010. See *Cedillo v. Sec'y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff'd*, 89 Fed. Cl. 158 (2009), *aff'd*, 617 F.3d 1328 (Fed. Cir. 2010). The theory 2 test cases, which rejected the theory relied upon by petitioner, were not appealed.

<sup>6</sup> This was a correct statement of the controlling authority at the time of respondent's filing. However, in *Cloer*, the Federal Circuit ruled that "equitable tolling applies to the Vaccine Act." *Cloer v. Sec'y, HHS*, 654 F.3d. 1322, 1340 (Fed. Cir. 2011) (overruling *Brice v. Sec'y, HHS*, 240 F.3d 1367 (Fed. Cir. 2001)).

<sup>7</sup> Petitioner attached a copy of the report from the Section of Child and Adolescent Psychiatry at the University of Chicago to her response, showing Kyra was diagnosed with autism in 2001. See Pet. Ex. 3, pp. 1, 4. Although petitioner indicates Kyra was diagnosed with autism on July 16, 2001, the report is not

7, 10. Petitioner alleges that Kyra’s “global development delay” alone is not a sufficient sign of autism, and therefore fails to trigger the running of the applicable statute of limitations under the Vaccine Act. *Id.* at 6-7. Alternatively, petitioner asserts that the doctrine of equitable tolling should apply to her claim. *Id.* at 8-10.

Following resolution of the OAP test cases,<sup>8</sup> petitioner was ordered to inform the court if she wished to proceed with her claim. Order, June 4, 2012, at 2-3. Because petitioner did wish to continue with her claim and petitioner’s counsel believed there was no reasonable basis to do so, counsel filed a motion to withdraw as attorney of record. Motion, filed Oct. 19, 2012, at 4-5. I deferred ruling on the motion to withdraw and ordered the parties to file briefs addressing the issue of whether the claim was timely filed. Order, filed Mar. 1, 2013. Specifically, I afforded petitioner an opportunity to address any circumstances that might warrant the application of equitable tolling, given the *Cloer* decision by the Court of Appeals for the Federal Circuit. *Id.*; see *Cloer*, 654 F.3d at 1340.

On April 1, 2013, petitioner filed her supplemental response, requesting that I apply the doctrine of equitable tolling to her claim since the Federal Circuit in *Cloer* held that “equitable tolling of the Vaccine Act’s statute of limitations is permitted.” Petitioner’s Supplemental Response [“Pet. Suppl. Response”] at 5. However, petitioner did not specify why the statute of limitations should be tolled in her case.

In her reply, respondent argues that the case was untimely filed and “does not merit equitable tolling.” Respondent’s Reply [“Res. Reply”], filed Apr. 15, 2013, at 2. Respondent asserts that the Federal Circuit’s holding in *Cloer* limited the application of equitable tolling to “extraordinary circumstances” and cautioned that it should be used “sparingly.” *Id.* at 1 (quoting *Cloer*, 654 F.3d at 1344). Respondent maintains “[t]he Federal Circuit expressly held that equitable tolling is not a substitute for the discovery rule and is not available simply because application of the statute of limitations would otherwise deprive a petitioner of her claim.” Res. Reply at 1.

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dated and shows only that Kyra was evaluated on July 16, September 5, and September 7, 2001 and diagnosed with autism. Pet. Response at 2; Pet. Ex. 3, pp. 1, 4. Respondent asserts that “Kyra was diagnosed with autism by March 28, 2001.” Res. Motion to Dismiss at 3 (referencing Pet. Ex. 1, p. 98 (medical records from oral surgery performed on March 28, 2001 which list both developmental delay and autism as preoperative diagnoses)).

<sup>8</sup> Decisions in each of the three test cases pertaining to the PSC’s first theory rejected the petitioners’ causation theories. *Cedillo v. Sec’y, HHS*, No. 98-916V, 2009 WL 331968 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 89 Fed. Cl. 158 (2009), *aff’d*, 617 F.3d 1328 (Fed. Cir. 2010); *Hazlehurst v. Sec’y, HHS*, No. 03-654V, 2009 WL 332306 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 473 (2009), *aff’d*, 604 F.3d 1343 (Fed. Cir. 2010); *Snyder v. Sec’y, HHS*, No. 01-162V, 2009 WL 332044 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *aff’d*, 88 Fed. Cl. 706 (2009). Decisions in each of the three “test cases” pertaining to the PSC’s second theory also rejected the petitioners’ causation theories, and petitioners in each of the three cases chose not to appeal. *Dwyer v. Sec’y, HHS*, No. 03-1202V, 2010 WL 892250 (Fed. Cl. Spec. Mstr. Mar. 12, 2010), 2010 WL 892250; *King v. Sec’y, HHS*, No. 03-584V, 2010 WL 892296 (Fed. Cl. Spec. Mstr. Mar. 12, 2010); *Mead v. Sec’y, HHS*, No. 03-215V, 2010 WL 892248 (Fed. Cl. Spec. Mstr. Mar. 12, 2010).

## II. Medical History.

Kyra was born on December 5, 1998. Pet. Ex. 1, p. 62. Her Apgar scores<sup>9</sup> were 9 at both one and five minutes. *Id.*, p. 86. The day she was born, Kyra received a hepatitis B vaccination.<sup>10</sup> Pet. Exs. 1, p. 67; 2, p. 1. The day after she was born, Kyra was noted to have a club foot and a cousin and siblings with autism. Pet. Ex. 1, p.72.

When Kyra was six months old, she began seeing pediatricians at La Rabida Children's Hospital and Research Center.<sup>11</sup> She had her six month well child examination on July 16, 1999. Pet. Ex. 2, pp. 56-60. Although no abnormal findings were documented, her pediatrician wrote "DD" in the assessment section of the record, suggesting that Kyra was developmentally delayed. *Id.*, p. 56. Under the "Family History" section, the words "Autism" and "? Autism" were written with regard to her older and younger brothers. *Id.*, p. 58. Her uncle was noted to have "mental retardation." *Id.*

On November 4, 1999, when she was nearly a year old, Kyra was seen for her nine month well child examination. Pet. Ex. 2, p. 52. The pediatrician noted clear developmental delay at this time. *Id.* Kyra had not reached many of the normal developmental milestones; she was not standing, walking while holding onto furniture, sitting, crawling, or playing repetitive games. *Id.*

At her one year well child examination on December 6, 1999, Kyra was exhibiting developmental delays, including decreased verbal skills, and self-stimulatory behaviors. Pet. 2, p. 48. In addition to not standing, walking, or playing repetitive games, Kyra was not scribbling spontaneously or using more than two single words. *Id.* The pediatrician recorded Kyra's global developmental delay and family history of PDD,<sup>12</sup> and referred her to genetic specialists, Drs. Dobyms and Waggoner. *Id.*, pp. 47, 49-50 (both doctors' names were misspelled in referral). He also ordered an audiological evaluation. *Id.*, p. 50.

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<sup>9</sup> An Apgar score is a numerical assessment of a newborn's condition (with lower numbers indicating problems), usually taken at one minute and five minutes after birth. The score is derived from the infant's heart rate, respiration, muscle ton, reflex irritability, and color, with from zero to two points awarded in each of the five categories. DORLAND'S ILLUSTRATED MEDICAL DICTIONARY ["DORLAND'S"] at 1682 (32<sup>th</sup> ed. 2012).

<sup>10</sup> From birth until April 30, 2002 (when she was 28 months of age), Kyra received the recommended childhood vaccinations. See Pet. Ex. 2, p.1. Kyra was administered the hepatitis B vaccine, the oral polio vaccine, the diphtheria-tetanus-acellular pertussis vaccine, the Haemophilus influenzae type b vaccine, and the measles, mumps, and rubella vaccine. *Id.*

<sup>11</sup> In notes from a visit on November 4, 1999, Kyra's pediatricians recorded that her mother brought her to the center due to her frustration with Kyra's former pediatrician. Pet. Ex. 2, p. 53.

<sup>12</sup> Pervasive developmental disorder ["PPD"] is the umbrella term for autism spectrum disorders ["ASDs"] used in the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 4th ed. text revision 2000) ["DSM-IV-TR"] at 69. The DSM-IV-TR has since been replaced by the Diagnostic and Statistical Manual of Mental Disorders (American Psychiatric Association, 5th ed. 2013) ["DSM-V"] which uses the term "autism spectrum disorder."

On January 14, 2000, at 13 months of age, Kyra was evaluated for overall developmental delays by Darrel Waggoner, M.D. at the University of Chicago's Genetics Clinic. See Pet. Ex. 1, pp. 2-4. Doctor Waggoner noted that Kyra's mother recognized six months earlier that Kyra was "not crawling, was not sitting up and was not reaching her milestones as one would predict." *Id.*, p. 2. He added that "[o]ver the past six months [Kyra] has made minimal gains in her development and continues to show marked delays" and that Kyra was receiving both physical and speech therapy at the time of her evaluation. *Id.*, p. 3. He ordered chromosomal testing. *Id.*, p. 4.

On March 23, 2000, Kyra received her 15 month well child examination. Pet. Ex. 2, p. 38. The notes from the examination indicate that she failed to meet many of her developmental milestones, including the ability to use two or more single words other than "mama" or "dada," and the ability to point to a named body part. *Id.* The notes also indicate that Kyra engaged in head banging. *Id.* Medical records from this time show that Kyra's mother was working with a family advocate, M. Fitzgerald. *Id.*, pp. 39-40.

On April 10, 2000, Kyra was seen in the Audiology Department at the University of Chicago Hospitals for an audiological evaluation. Pet. Ex. 1, p. 7. The results of that evaluation were normal. *Id.*

On September 5, 2000, when she was 21 months of age, Kyra visited her pediatrician for a check up. Pet. 2, p. 35. Kyra was "[j]ust starting to walk," and said only "mama," "baba," and "No." *Id.* The medical records from this visit indicate x-rays of Kyra were taken on May 19, 2000, and she was found to have rickets.<sup>13</sup> *Id.* Kyra saw her pediatrician again on September 19, 2000, for a follow-up appointment regarding her rickets. *Id.*, p. 31.

On September 20, 2000, Kyra visited her pediatrician for an autism evaluation. Pet. Ex. 2, p. 29. She was beginning to get aggressive with her brothers. *Id.* Kyra was assessed as "[p]robably not autistic." The "Developmental Milestones" section reflected that she only said "Ma Ma – Bye Bye". *Id.*

On October 3, 2000, Kyra was seen for follow-up regarding her rickets. Pet. Ex. 2, p. 26. She attended her 24 month well child examination on November 7, 2000, and was noted to have developmental delay and rickets. On November 28, 2000, Kyra was seen by Dianne Deplewski, M.D. at the Pediatric Endocrinology Department of the University of Chicago Children's Hospital for her previous diagnosis of rickets. Pet. Ex. 1, pp. 30-31. Dr. Deplewski stated that Kyra "has a history of developmental delay which was diagnosed at six or seven months of age." *Id.*, p. 30.

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<sup>13</sup> Rickets is "an interruption in the development and mineralization of the growth plate of the bone with radiographic abnormalities, osteomalacia, bone pain, fatigability, growth retardation, and often hypotonia, convulsions and tetany." DORLAND'S at 1644.

In 2001,<sup>14</sup> Kyra was officially diagnosed with autism by Stephen J. Guter, Jr., M.A., Jeff Salt, a clinical psychologist, and Edwin Cook Jr., M.D.<sup>15</sup> Pet. Ex. 3, pp. 4-5. They noted that “Kyra’s mother first became concerned about her development when Kyra was 16 months old because she had not started to talk . . . and [that] [m]ost of Kyra’s early milestones were delayed.” *Id.*, p. 1. They further observed that “Kyra’s non-verbal and verbal communication skills are starting to emerge.” *Id.* Concluding that Kyra showed signs of impairment in communication, impairment in reciprocal social interactions, and atypical patterns of play and interests, they diagnosed her with autism. *Id.*, p. 4. In particular, they determined Kyra exhibited delayed speech, limited or no gestures, lack of eye contact, limited affect, infrequent social initiations, and lack of joint attention behavior. *Id.*

### III. Statute of Limitations.

The Vaccine Act provides that:

In the case of . . . (2) a vaccine set forth in the Vaccine Injury Table which is administered after October 1, 1988, if a vaccine-related injury occurred as a result of the administration of such vaccine, no petition may be filed for compensation under the Program for such injury after the **expiration of 36 months** after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury . . . .

§ 16(a)(emphasis added).

In *Cloer*, the Court of Appeals for the Federal Circuit affirmed that “the first symptom or manifestation of onset of a vaccine-related injury is ‘the first event objectively recognizable as a sign of a vaccine injury by the medical profession at large.’” *Cloer*, 654 F.3d. at 1335 (*quoting Markovich v. Sec’y, HHS*, 477 F.3d 1353, 1360 (Fed. Cir. 2007)). In *Wilkerson*, the Federal Circuit explained that the “recognition may have occurred some time after the symptoms first occurred.” *Wilkerson v. Sec’y, HHS*, 593 F.3d 1343, 1346 (Fed. Cir. 2010).

The Federal Circuit has held that “[t]here is no requirement that the vaccine injury be diagnosed.” *Cloer*, 654 F.3d at 1329 (emphasis omitted). The Circuit determined the date of the first symptom or manifestation of injury is “a statutory date that does not depend on when a petitioner knew or reasonably should have known anything adverse

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<sup>14</sup> The report is not dated and shows only that Kyra was evaluated on July 16, September 5, and September 7, 2001 and diagnosed with autism. Pet. Ex. 3, pp. 1, 4.

<sup>15</sup> The diagnostic report indicates stated that Kyra showed signs of impairment in communication, impairment in reciprocal social interactions, and atypical patterns of play and interests. Pet. Ex. 3, p. 5. Kyra’s non-verbal cognitive skills were within the mild range of handicap, and her adaptive skills were within the mild to moderate range of handicap. *Id.* Her verbal cognitive skills were within the severe range of handicap. *Id.*

about her condition.” *Cloer*, 654 F.3d at 1339. The date is dependent on when the first sign or symptom of injury appears, not when a petitioner discovers a causal relationship between the vaccine and the injury. *Id.*

Although the Federal Circuit held that doctrine of equitable tolling applies to Vaccine Act claims, the Circuit explained that it is only available in “extraordinary circumstances,” such as when a petitioner is the victim of fraud or duress. *Id.* at 1344-45 (citing *Pace v. DiGuglielmo*, 544 U.S. 408, 418 (2005)). In *Cloer*, the Circuit declined to apply equitable tolling because the petitioner did not know of a causal link between her injury and vaccination until 2004. 654 F.3d at 1344-45. The Circuit specifically held “that equitable tolling under the Vaccine Act due to unawareness of a causal link between an injury and administration of a vaccine is unavailable.” *Id.* at 1345.

#### IV. Analysis.

##### A. First Symptom or Manifestation of Onset.

In the petition, petitioner alleges that the vaccines Kyra received caused her developmental problems but, in later filings petitioner focuses on Kyra’s autism, implying it is the vaccine-caused injury. *Compare* Petition at 1 *with* Pet. Response at 2, 5-6. Since some of Kyra’s earlier developmental problems would not constitute a symptom of autism, I base my determination on timely filing by considering when symptoms of autism first manifested.<sup>16</sup>

In her response to the motion to dismiss, petitioner asks that I not dismiss her claim because Kyra’s “condition was not recognized by a medical professional until July 16, 2001,” when she was evaluated and officially diagnosed<sup>17</sup> with autism. Pet. Response at 2, 6. As discussed in Section III, Kyra need not have a recognized condition and a diagnosis is not required to trigger the running of the statute. See *Cloer*, 654 F.3d at 1329. Rather, the Vaccine Act’s statute of limitations begins to run when Kyra exhibits a first symptom or manifestation of autism as recognized by the medical profession at large. See *id.* at 1335.

Examining the medical records filed in this case, it is clear that Kyra was exhibiting speech delay at her 15 month well child examination on March 23, 2000. Pet. Ex. 2, p. 38. Additionally, it was noted that she was unable to point to a body part and engaged in head banging. *Id.* She was noted as having decreased verbal skills at her one year well child examination on December 6, 1999. *Id.*, p. 48. As early as January 14, 2000, Kyra was receiving both physical and speech therapy. Pet. Ex. 1, p. 3. At Kyra’s evaluation for autism in 2001, it was noted that “Kyra’s mother first became

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<sup>16</sup> Kyra’s developmental delay was apparent as early as November 4, 1999, during her nine month well child examination and possibly on July 16, 1999, during her six month well child examination. See Pet. Ex. 2, pp. 52, 56. Thus, if petitioner is claiming developmental delay as the vaccine-caused injury, the petition is untimely filed by more than seven months.

<sup>17</sup> It is not clear that Kyra was diagnosed on July 16, 2001. See *supra* note 7.

concerned about her development when Kyra was 16 months old because she had not started to talk.” Pet. Ex. 3, p. 1. Kyra was 16 months old on April 5, 2000.

As the Federal Circuit held recently in *Carson*, speech delay can qualify as “the first objectively recognizable symptom of autism.” *Carson ex rel. Carson v. Sec’y, HHS*, \_\_\_ F.3d \_\_\_, 2013 WL 4528833, at \*3 (Fed. Cir. 2013). It does not matter that it may not be sufficient for a diagnosis of autism, “may be indicative of a variety of conditions or ailments,” or that a lay person may not “appreciate the medical significance” of the speech delay. *Carson*, 2013 WL 4528833, at \*3 (quoting *Markovich*, 477 F.3d at 1357).

Since the petition was filed on June 12, 2003, the claim is untimely filed if Kyra exhibited her first symptom or manifestation of onset of autism prior to June 12, 2000. The medical records document that Kyra exhibited symptoms of autism, including speech delay, the inability to point to a body part, and repetitive behaviors such as head banging, prior to June 12, 2000. Thus, I find that the petition in this case was not timely filed.<sup>18</sup>

## **B. Equitable Tolling.**

Petitioner argues that equitable tolling should apply to her case because she did not and could not know the factual basis for her claim. Petition at 1. However, this argument was rejected by the Federal Circuit in *Cloer*. 654 F.3d at 1344-45. The Federal Circuit specifically held that the fact that petitioner does not know of a potential causal link between injury and vaccine is not “the sort of circumstance that might merit equitable tolling.” *Id.*

Although I am sympathetic to petitioner’s desire to avoid a dismissal on the grounds that the petition was untimely filed, I cannot apply equitable tolling to her case, based on the circumstances she presented. Petitioner has not alleged, nor does it appear there is any basis to allege, that she was prevented from filing a timely petition because she was a victim of fraud, duress, or other extraordinary circumstances. See *Cloer*, 654 F.3d at 1344.

Petitioner has not presented any arguments that would support the application of equitable tolling to this claim, and my examination of the record does not disclose any basis for applying equitable tolling to this case.

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<sup>18</sup> Again, if Kyra’s injury is deemed to be developmental delay as alleged in her petition rather than autism, the Vaccine Act’s statute of limitations would have begun to run at an even earlier date. Kyra was exhibiting developmental delay as early as November 4, 1999, and possibly even as early as July 16, 1999. Pet. Ex. 2, pp. 52, 56.

## V. Conclusion.

Petitioner has the burden to show timely filing. Petitioner has failed to do so. There is preponderant evidence that this case was not filed within “36 months after the date of the occurrence of the first symptom or manifestation of onset or of the significant aggravation of such injury” as required by the Vaccine Act. § 16(a)(2). Furthermore, petitioner has not demonstrated any extraordinary circumstances warranting equitable tolling. **Thus, this claim is dismissed as untimely filed under the Vaccine Act’s statute of limitations. The Clerk is directed to enter judgment accordingly.**

**IT IS SO ORDERED.**

**s/Denise K. Vowell**

**Denise K. Vowell**

Special Master